

REMARKS

Reconsideration of this application is respectfully requested.

Claims 35-44 have been canceled. New claims 45-56 are derived from canceled claims 35-44. No new matter is introduced through this amendment.

Rejections under 35 U.S.C. § 101

Claims 35-38 and 40-43 were rejected under 35 U.S.C. § 101 as allegedly being drawn to non-statutory subject matter. The Office Action asserts that applicants' claimed mammalian embryos and mammals are not distinguished over a mammalian embryo or mammal found in nature. Specifically, the Office Action contends that the claimed mammalian embryos and mammals are produced by a particular process, but are not altered by the process so that the "hand of man" is present. Applicants traverse the rejection.

Applicants claimed mammalian embryos and mammals are cloned mammalian embryos and mammals. Applicants' new claims 45-54 further recite the phrase "clone of a pre-existing, non-human, non-embryonic mammal" to emphasize this novel aspect of applicants' invention. Without the intervention of man, applicants' clones would not exist.

A single parental animal provides the chromosomes of the clone, which is asexually reproduced. This is not the case with mammals found in nature. Mammals found in nature arise from the combination of chromosomes from two distinct parents and are sexually reproduced. In this important aspect, applicants' clones are unlike any mammalian embryos and mammals that exist in nature. Thus, the "hand of man" must be present to create applicants' clones.

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The Office's position is contrary to legal precedent set forth by the Supreme Court in *Diamond v. Chakrabarty*, 447 U. S. 303, 206 U.S.P.Q. 193 (1980). In *Chakrabarty*, the Supreme Court indicated that Congress intended statutory subject matter to include **anything under the sun that is made by man**. 447 U.S. at 309, 206 U.S.P.Q at 197. There can be no doubt that applicants' claimed clones are made by man and do not exist in nature. Thus, they must be considered statutory subject matter. See *id.* Accordingly, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 35, 38, 39, 40, 43, and 44 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action asserts that claims 39 and 40 are unclear in whether the resultant embryo or mammal has the same set of chromosomes as a nonhuman, non-embryonic mammal of the same species. The Office Action also alleges that claims 38 and 43 are unclear in the meaning of the phrase "wherein the cell is abstracted ex vivo." Applicants traverse the rejection.

The Office Action gives no reasons why claims 35 and 40 were included in this rejection. Accordingly, applicants submit that the rejection of claims 35 and 40 is improper.

Applicants disagree with the Office's characterization of claims 39 and 44 as meaning that the transferred cell is from a transgenic mammal. As described in the specification, transgenic animals can be produced from genetically altered donor cells. (Specification at 5, lines 31-33.) Gene targeting permits subtle genetic alteration. (*Id.* at 6, lines 7-8.) The specification describes that genetic modifications may take place prior to nuclear transfer. (*Id.* at 7, lines 6-8.) The specification describes genetic modification

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during cloning. (*Id.* at 19, lines 16-28.) Applicants' new claims 53 and 55 make clear that genetic modification takes place during cloning. Accordingly, applicants respectfully request withdrawal of the rejection.

Applicants disagree with the Office's characterization of claims 38 and 43 as meaning that the cells are isolated from multicellular embryos. Applicants submit that the ordinary meaning of "wherein the cell is abstracted *ex vivo*" would be clear to the skilled artisan from the specification, particularly page 8, lines 13-19. The skilled artisan would understand from the specification that cells "abstracted *ex vivo*" are cells that are taken from the body of an animal. Accordingly, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102(b)

Claims 34-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,057,420 (Massey). The Office Action alleges that Massey teaches bovine embryos isolated from artificially inseminated cows. The Office Action contends that the source of the embryo's chromosomes does not affect the embryo. Applicants traverse the rejection.

Anticipation under 35 U.S.C. §102 requires that every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383, 58 U.S.P.Q.2d 1286, 1291 (Fed. Cir. 2001).

Massey's embryos cannot anticipate applicants' embryos because Massey's embryos are missing a material limitation of applicants' claimed embryos. Applicants' embryos, unlike the embryos of Massey, are **clones**. The Office Action appears to

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have ignored this material limitation of applicants' claims. That applicants' claimed embryos are **clones** is an important difference between the claimed invention and the prior art. In view of this important difference, applicants' claimed embryos cannot be considered identical or substantially identical in structure or composition to Massey's embryos. Thus, the Office has not established a *prima facie* case of anticipation.

Applicants' embryo clones are the progeny of a single parent and have the same set of chromosomes as that parent. They are asexually reproduced. This is not the case with Massey's embryos. Massey's embryos have a set chromosomes from **two** parents and are sexually reproduced. Therefore, Massey's embryos cannot anticipate applicants' embryos. See *id.*

Applicants disagree with the Examiner's contention that the source of an embryo's chromosomes does not affect the embryo. The Examiner has cited no evidence in support of this contention. If the Examiner is relying on facts within the personal knowledge of the Examiner in making this rejection, applicants respectfully request that the Examiner provide an affidavit in support of this contention. See M.P.E.P. § 2144.03.

In contrast to the Office's contention, an embryo's characteristics are defined by its chromosomes together with environmental factors. Applicants submit Ayala et al., 1980 (Exhibit 1), as evidence that the observable characteristics of an individual (phenotype) result from the interaction between the genotype of an individual and the environment in which development occurs. Thus, the source of an embryo's chromosomes has a profound effect on an embryo's characteristics.

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An embryo that receives its set of chromosomes through sexual reproduction from two parents will not be identical or substantially identical to an embryo clone that receives its set of chromosomes asexually through cloning. Only the embryo that receives its full set of chromosomes from a single parent will be a clone of that parent. An embryo that receives its set of chromosomes from two parents will be a mixture of the genetic material of the two parents. The mixture of genetic material will have profound effects on the characteristics of the embryo. Massey's embryos have a mixture of the genetic material of two parents. Massey's embryos are not clones. Therefore, Massey's embryos cannot anticipate applicants' embryos.

In addition, applicants' claimed embryos and mammals had never existed prior to applicants' invention. Due to environmental factors, applicants' clones would differ from even the parental mammal. For example, applicants' clones would have different fingerprints, different irises, different retinas, and different skin and fur pigmentation patterns. As objective evidence of the existence of these differences, applicants provide Prather at 10 (Exhibit 2), U.S Patent 4,641,349 of Flom et al. at 4 (Exhibit 3), and an on-line article by Wells et al. at 1003 (Exhibit 4). As taught in these references, a clone will not be completely identical to its parent. Accordingly, a clone cannot be anticipated by its parent.

Claims 40-43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Campbell and Marshall, 1975. The Office Action alleges that Campbell and Marshall teach bovines that existed prior to applicants' invention. Applicants traverse the rejection.

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Similar to the embryos of Massey, Campbell and Marshall's bovines are sexually produced. Consequently, Campbell and Marshall's bovines have a mixture of the genetic material of two parents. They are not **clones** of a single parent. Campbell and Marshall's bovines are missing this important limitation of applicants' claimed mammals. Accordingly, Campbell and Marshall's bovines cannot anticipate applicants' claimed mammals.

Claims 34-38 and 40-43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sims et al., 1993. The Office Action alleges that Sims et al. teaches bovines and bovine embryos produced by nuclear transfer with a nuclear donor that is from a bovine cultured inner cell mass cell. Applicants traverse the rejection.

Sims' bovines and bovine embryos cannot anticipate applicants' mammals and embryos because Sims' bovines and bovine embryos do not have every element and limitation of the claimed invention. Applicants' mammals and embryos are clones of a pre-existing, non-embryonic parent and have the same set of chromosomes as that pre-existing, non-embryonic parent. This is not the case with Sims' bovines and bovine embryos. Sims' bovines and bovine embryos were made by nuclear transfer from embryonic, cultured inner cell mass cells. Thus, they have the same set of chromosomes as an embryonic, cultured inner cell mass cell. The embryonic, cultured inner cell mass cell received its set of chromosomes from two parents. Consequently, Sims' bovines and bovine embryos have a mixture of the genetic material of two non-embryonic parents. Sims' bovines and bovine embryos are not clones of a pre-existing, non-embryonic parent. Accordingly, Sims' bovines and bovine embryos cannot anticipate applicants' mammals and embryos.

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Claims 39 and 44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Stice, 1993. The Office Action alleges that Stice teaches transgenic non-human mammals and embryos produced by nuclear transfer with a nuclear donor that is an embryonic cell comprising a genetic modification. Applicants traverse the rejection.

Stice's bovines and bovine embryos cannot anticipate applicants' mammals and embryos because Stice's mammals and embryos do not have every element and limitation of the claimed invention. Applicants' mammals and embryos are clones of a pre-existing, non-embryonic parent and have the same set of chromosomes as that pre-existing, non-embryonic parent. This is not the case with Stice's mammals and embryos. Stice's mammals and embryos were made by nuclear transfer from an embryonic cell. Thus, Stice's mammals and embryos have the same set of chromosomes as the embryonic cell. The embryonic cell received its set of chromosomes from two parents. That is, the embryonic cell was formed by sexual reproduction. Consequently, Stice's mammals and embryos have a mixture of the genetic material of two pre-existing, non-embryonic parents. Sims' bovines and bovine embryos are not clones of a pre-existing, non-embryonic parent. Accordingly, Stice's mammals and embryos cannot anticipate applicants' mammals and embryos.

Conclusion

Applicants respectfully submit that this application is now in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice of Allowance, applicants respectfully request that the Examiner contact the undersigned to discuss any outstanding issues.

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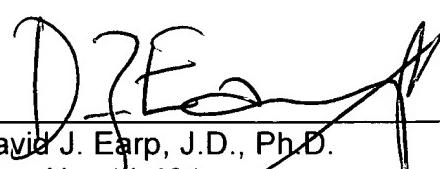
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If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 07/1139.

Respectfully submitted,

Dated: June 19, 2002

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